American College of Radiology™

August 28, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Electronically Submitted: https://www.federalregister.gov/documents/2023/06/27/2023-13544/medicare-program-transitional-coverage-for-emerging-technologies

Re: **Medicare Program: Transitional Coverage for Emerging Technologies (CMS-3421-NC)**

Dear Administrator Brooks-LaSure:

The American College of Radiology (ACR) representing more than 41,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists, appreciates the opportunity to submit public comments in response to the Centers for Medicare and Medicaid Services (CMS) notice with comment period on the process used to provide transitional coverage for emerging technologies (TCET) through the national coverage determination (NCD) process. ACR concurs with CMS that new approaches are needed to make decisions on certain new items and services more quickly to provide expedited access to emerging innovative medical technologies. We support accelerating the Medicare coverage determination process and making it more transparent.

CMS justifies the establishment of the TCET pathway by noting that "Medicare beneficiaries are often older, with multiple comorbidities, and are often underrepresented or not represented in many clinical studies" and that "the potential benefits and harms of a device for older patients with more comorbidities may not be well understood at the time of U.S. Food and Drug Administration (FDA) market authorization. By ensuring timely coverage of emerging technologies, TCET would provide Medicare beneficiaries with a broader range of treatment options. This would enable Medicare beneficiaries, in consultation with their doctor, to make informed, personalized decisions about their care.

ACR recommendations to strengthen the TCET Pathway:

- In addition to traditional clinical study designs, CMS should permit the use of fit-for-purpose studies that structure the study design, analysis plan, and study data to target specific questions in Evidence Development Plans.

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- CMS, in coordination with FDA, should maintain each Agency's website with an up-to-date list of all devices in the FDA's Breakthrough Device program that are being considered for CMS' TCET program.
- CMS should evaluate its current NCD pathway to ensure efficient market access for advanced imaging solutions and software, novel radiopharmaceuticals and contrast agents, and high-intensity focused ultrasound therapies.
- Earlier guidance from CMS on how to coordinate coding and payment applications to secure Medicare reimbursement is needed for emerging technologies.
- CMS should communicate with specialty societies regarding relevant opportunities to provide feedback and encourage CMS to be flexible regarding the time it takes specialty societies to collect evidence and determine consensus perspectives as they pertain to coverage decisions.
- CMS should require manufacturers to submit clinical data information within and throughout the TCET coverage cycle.
- CMS should consider adding more staff and assessing resource constraints to streamline this new program and offer guidance to innovators that will expedite coverage for Medicare beneficiaries.
- CMS should include detailed TCET program information in its report to Congress on Medicare National Coverage Determinations.
- CMS will need to continue to work with medical technology innovators, medical specialty societies, healthcare providers, patients, and others to improve and expedite the path from FDA marketing authorization to CMS coverage.
- An NCD that requires CED as a condition of coverage should not last indefinitely, including under the TCET pathway.

We support the development of a voluntary, time-limited pathway for emerging technologies. However, ACR has some concerns about the scope and utility of the program as proposed. We are concerned that TCET will not address certain fundamental coverage, coding, and payment issues facing innovative technologies and will not adequately support the volume of new products coming to the market. Appropriate candidates for the TCET pathway include devices with a Medicare benefit category but do not address the need to reexamine the definition of existing benefit categories to include many innovative devices. Overreliance on this criterion will leave emerging technologies without appropriate Medicare reimbursement under the TCET pathway.

The TCET program outlines an expedited pathway for FDA-designated Breakthrough Devices to qualify for Medicare coverage. CMS created the TCET pathway to provide a mechanism for coverage for certain new, innovative technologies with limited or developing evidence in the Medicare population demonstrating the technology is reasonable and necessary for the diagnosis or treatment of an illness or injury. The TCET pathway will use the NCD and CED processes to expedite Medicare coverage of certain FDA-designated Breakthrough Devices. The pathway

provides manufacturers with opportunities for increased pre-market engagement with CMS and a new way to address any evidence gaps for coverage. CMS expects coverage under the TCET pathway to last three to five years to generate evidence to address identified evidence gaps.

Under the TCET pathway:

- Manufacturer participation is voluntary.
- CMS may conduct an early evidence review (Evidence Preview) before the FDA decides on marketing authorization for the device and discuss with the manufacturer the best available coverage pathways depending on the strength of the evidence.
- CMS may initiate discussions with manufacturers about any evidence gaps for coverage purposes and the types of study designs that could address them before FDA marketing authorization. The manufacturer may then propose an Evidence Development Plan (EDP). As part of the EDP development process, CMS would work with manufacturers to efficiently meet both CMS evidence development and FDA post-market requirements.

CMS' goal is to finalize a TCET NCD within six months after FDA market authorization. It intends to have coverage under the TCET NCD continue only as long as is needed to facilitate the timely generation of evidence that can inform patient and clinician decision-making. CMS intends to conduct an updated evidence review plan within 6 months of the review date specified in the EDP. Based upon the updated evidence review and consideration of any applicable practice guidelines, CMS will open an NCD determination which could propose (1) an NCD; (2) an NCD with CED; (3) a non-coverage NCD; or (4) decision by the Medicare Administrative Contractors (MACs).

CMS is proposing that certain devices will be candidates for the TCET pathway, including those that meet the following criteria:

- FDA-designated Breakthrough Devices,
- Determined to be within a Medicare benefit category,
- Not already the subject of an existing Medicare NCD, and
- Not otherwise excluded from coverage through law or regulation.

Under the proposal, Medicare coverage under the TCET pathway is limited to certain Breakthrough Devices that receive market authorization for one or more indications for use covered by the Breakthrough Device designation when used according to those indications for use. Manufacturers of FDA-designated Breakthrough Devices that fall within a Medicare benefit category may self-nominate to participate in the TCET pathway voluntarily. FDA proposed via a 2022 draft guidance update (FDA-2022-D-1061) to be able to publicly share Breakthrough Device designation following device sponsor disclosure, which may sometimes be done before authorization to attract investment or interest. However, absent a device sponsor's business decision to publicly disclose their designation, there is no mechanism for public stakeholders to know that a device is in the Breakthrough Device program before that device is authorized by FDA. Moreover, FDA is unable to request public comment on devices under initial consideration

for Breakthrough designation. **To further enhance transparency, we would encourage CMS, in coordination with FDA, to maintain each Agency's website with an up-to-date list of all devices in the FDA's Breakthrough Device program that are being considered for CMS' TCET program**.

The very limited scope of this proposal is particularly concerning for medical imaging given the small number of imaging products that currently have "Breakthrough" status. Our industry continues to innovate and has numerous advanced artificial intelligence (AI) and machine learning (ML) solutions in development that may not qualify for "Breakthrough" designation and have an uncertain pathway to appropriate coding, coverage, and payment. Much of the focus has been on CMS examining health outcomes and their clinically meaningful differences within therapeutic areas, but less attention has been given to the diagnosis of the patient before starting any kind of treatment. We strongly support both policy and process improvements that would result in a predictable pathway to national Medicare coverage for new medical devices and diagnostics. **ACR suggests CMS should also evaluate its current NCD pathway to ensure efficient market access for advanced imaging solutions and software, novel radiopharmaceuticals and contrast agents, and high-intensity focused ultrasound therapies**.

CMS believes that the TCET pathway can support manufacturers that are interested in working with CMS to generate additional evidence that is appropriate for Medicare beneficiaries, which may demonstrate improved health outcomes in the Medicare population to support more expeditious national Medicare coverage. Gaining coverage for innovative products is only one step on the longer pathway to Medicare beneficiary access. Unless these products also have a transparent, predictable, and expedient pathway to appropriate coding and payment, they will continue to face serious challenges to adoption. **Earlier guidance from CMS on how to coordinate coding and payment applications to secure Medicare reimbursement is needed for emerging technologies.**

The TCET proposal should be designed to engage the physician community in discussions concerning coverage for medical technologies throughout the pathway and not just during public comment. Although CMS does request specialty societies and patient advocacy groups' input on the evidence base and conditions of coverage, we recommend CMS allow the opportunity for earlier input during the development of the Evidence Preview. **ACR appreciates CMS' recognition that medical specialty societies "have valuable expertise and first-hand experience in the field that will help CMS develop Medicare coverage policies. We will continue to monitor the opening of a TCET NCD analysis and offer guidance where possible. We urge CMS to communicate with specialty societies regarding relevant opportunities to provide feedback and encourage CMS to be flexible regarding the time it takes specialty societies to collect evidence and determine consensus perspectives as they pertain to coverage decisions.**

The ACR believes CMS should require manufacturers to submit clinical data information within and throughout the TCET coverage cycle. A phased-in approach with data submission beginning early through an EDP after FDA authorization will help the Agency identify adverse events, utilization among Medicare beneficiaries, and improvements in healthcare outcomes. This process will improve transparency and assist with an appropriate coverage process once the TCET pathway ends. We implore CMS to finalize the recent proposals to streamline Medicare coverage policies through coverage guidance documents based on our feedback provided to the Agency recently. If CMS determines that further evidence development through a CED is the best coverage pathway, the Agency should work with relevant stakeholders to reduce the burden on manufacturers, clinicians, and patients while maintaining rigorous evidence requirements. CMS has agreed to ensure they will not require duplicative or conflicting evidence development with any FDA post-market requirements for devices.

In the TCET proposal, CMS anticipates the program will only accept a limited number of products per year. Specifically, CMS anticipates accepting five candidates to participate in the TCET pathway each year. CMS indicates they will prioritize medical devices that have the potential to benefit the greatest number of individuals within the Medicare program. This is highly concerning given ongoing advances across the medical technology field. **ACR recommends CMS consider adding more staff and assessing resource constraints to streamline this new program and offer guidance to innovators that will expedite coverage for Medicare beneficiaries**.

We understand coverage under the TCET pathway depends on CMS acceptance of a candidate for this new pathway. When a device is accepted into the TCET pathway and receives FDA marketing authorization, CMS will initiate the NCD process by posting a tracking sheet, pending CMS and AHRQ-approved EDP. **To increase transparency, we recommend CMS include detailed TCET program information in its report to Congress on Medicare National Coverage Determinations.** [1] This report will add a level of accountability that will inform the public and CMS of the resources needed to support this new program and the time it takes to complete and implement TCET NCDs. Key aspects of the report will include adherence to statutory timeframes, implementation of the payment and coding changes for NCDs, and insight into nominations that were not completed based on discussions between the manufacturer, CMS, AHRQ, and FDA. Specifically, if an EDP is not approved, CMS may withdraw coverage of the device from the TCET pathway.

We urge CMS to continue to work with medical technology innovators, medical specialty societies, healthcare providers, patients, and others to improve and expedite the path from FDA marketing authorization to CMS coverage. We agree with CMS that an NCD that requires CED as a condition of coverage should not last indefinitely, including under the TCET pathway. If the evidence supports a favorable coverage decision under CED, coverage

[1] https://www.cms.gov/files/document/2021-report-congress.pdf

should be time-limited to facilitate the timely generation of sufficient evidence to inform patient and clinician decision-making and to support a Medicare coverage determination.

The ACR appreciates the opportunity to submit recommendations to CMS on the proposed Transitional Coverage for Emerging Technologies program. If you have any questions or comments on our letter, please do not hesitate to contact Alicia Blakey MS, Principal Economic Policy Analyst, at ablakey@acr.org.

Respectfully submitted,

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Chief Executive Officer

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